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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/475,548 12/30/99 STEWARD

J M-7891-US

EXAMINER

QM12/0727

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ART UNIT

PAPER NUMBER

3763

DATE MAILED:

07/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/475,548	STEWARD ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	LoAn H Thanh	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 May 2001.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6,8-10 and 14-16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-5,7,11-13 and 17-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 30 December 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of species D – fig. 8 in Paper No. 7 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has not argued that the species are not patentably distinct. See last office action paragraph 2.

Claims 6, 8-10, 14-16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species B, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

An action on the merits will now follow.

### ***Drawings***

The drawings are objected to because it is unclear how the tissues can be inside the balloon wall. The tissue should be surrounding the balloon wall and not the reverse. No figure 9, which is disclosed on page 14.

Correction is required.

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

### ***Specification***

The disclosure is objected to because of the following informalities:

Reference numeral 36 has been designated both as "catheter tube" and "delivery/electrical lumen". See page 9 line 15, 20.

Reference numeral 44 has been designated both as "distal end" and "distal portion". See page 8, line 22 and page 12, line 28.

Reference numeral 32 has been designated both as "catheter tube" and "distal portion". See page 13, line 1.

No brief description for fig. 9 as disclosed on page 14.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7, 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 7 are vague and indefinite because it is unclear whether applicant is intending to claim a Markush grouping claim or not. If so, it is suggested to insert "group consisting of" into the claim. If not then it is suggested to delete "and" and insert "or".

Claim 7 is vague and indefinite because "said at least one therapeutic substance" lacks proper antecedent basis. Applicant has established the at least therapeutic agent in the preamble but has not positively claim it in the body of the claim. It is unclear

whether applicant is intending to only functionally claim the therapeutic substance or whether it is a combination/subcombination claim.

Claim 17 is vague and indefinite because "the catheter assembly" in line 7 lacks proper antecedent basis. It is unclear whether applicant intended it to be "the catheter" only.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*11-13*

Claims 1-5, 7, ~~11, 12~~ 13, 17-20 are, rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brisken et al.

See figs. 2-14, specifically 11.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038.

If attempts to reach the examiner by telephone are unsuccessful, Richard Seidel, can be reached on (703) 308-5115. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

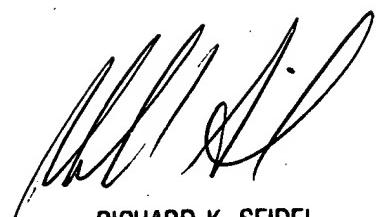
Any inquiry of a general nature or relating to the status of this application or

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proceeding should be directed to the receptionist, whose telephone number is  
(703) 308-0858.

LoAn H. Thanh  
Patent Examiner  
Art Unit: 3763  
Date: July 26, 2001



RICHARD K. SEIDEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700